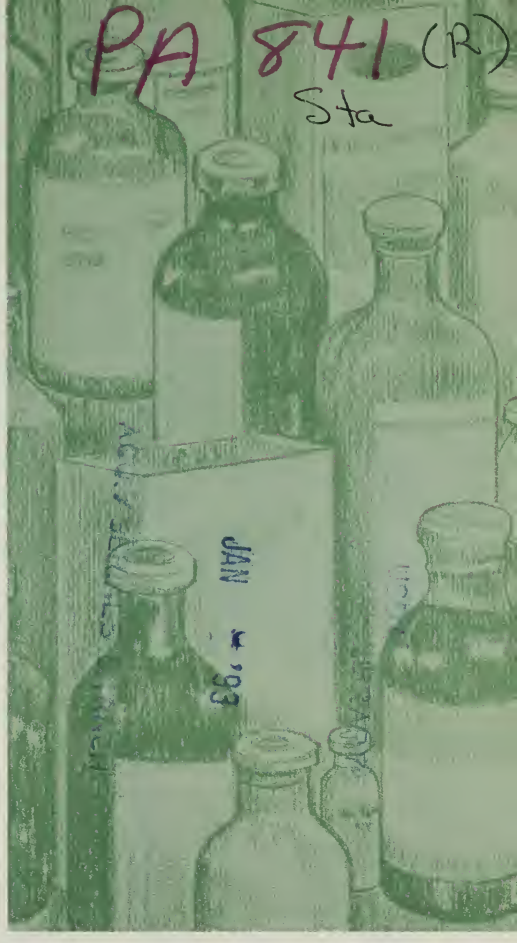
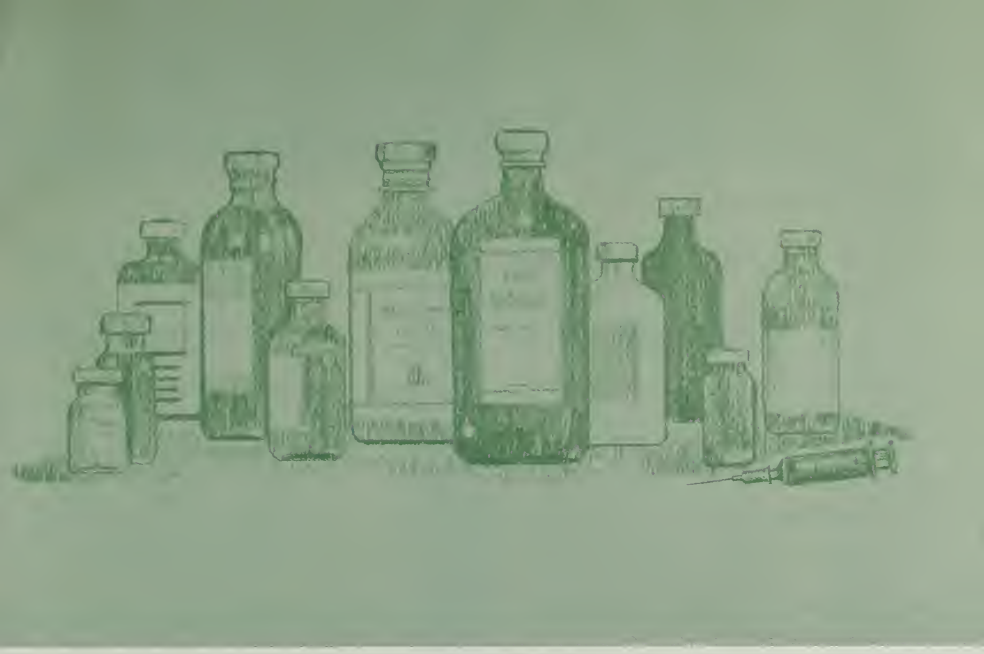


care and use of veterinary biologics

VETERINARIAN'S CHECK LIST

U.S. Department of Agriculture ▪ Program Aid No. 841 (R)

Veterinarians select biologics from an array of some 260 different kinds of U.S. licensed products and use them to diagnose, prevent, or treat about 60 animal diseases.



biologics require QUALITY CONTROL

Most veterinary biologics do the job for which they were intended. Some fail because they are mishandled or incorrectly administered. Even a small percentage of failures is too costly to tolerate because disease control is essential to efficient animal agriculture. For example, a 1-percent failure rate for the 8 to 9 billion doses of vaccines administered each year would leave 80 to 90 million animals unprotected against disease.

For more than a half-century, the U.S. Department of Agriculture has regulated the interstate marketing of veterinary biologics to help assure that animal vaccines, serums, antitoxins, and other biologics are the best that science can provide to protect our $28 billion livestock and poultry industries. The biologics industry has responded to regulations and to needs of farmers and ranchers by developing and improving biologics that meet increasingly higher standards.

In the process of licensing and regulating manufacturers of veterinary biologics, USDA inspects production plants, designates industry testing procedures, oversees labeling of products, and subjects biologics to various tests for purity, safety, and potency. These measures and the safeguards employed by industry help assure that only pure, safe, and effective biologics reach the market.

users share RESPONSIBILITIES

USDA's regulatory authority does not extend to handlers and users of veterinary biologics. The task of keeping a product safe and effective after it leaves the production plant lies ultimately with the handler and the veterinarian who administers the biologic. How diligently this task is carried out bears importantly on the protection of animals, the integrity of the biologic, and professional reputation of the veterinarian.

mishandled biologics may be DANGEROUS

Improper handling during marketing, storage, and use can rapidly degrade biologics and make them inert, or convert them from beneficial disease fighters to dangerous disease spreaders. Subtle changes may cause them to lose potency; contamination may make them dangerous.

An ineffective vaccine poses a double barreled problem: You can't look at the vaccine and detect deterioration with any degree of certainty; and you can't look at an animal vaccinated with the product and detect failure to develop immune response. Unfortunately, the first signs of failure may be an unexpected and costly outbreak of the disease that vaccination was supposed to prevent.

Failure of vaccine users to follow manufacturers' directions is one of the most frequent causes of ineffective vaccination.

veterinary biologics . . . checklist

Before Administering

- ☑ DETERMINE how biologics are handled from the manufacturer's plant until you receive them. Biologics should be kept cool during shipment.
- ☑ BUY just enough biologics for your immediate needs; don't store extra amounts.
- ☑ CHECK labels and literature for special storage and handling instructions.
- ☑ STORE biologics in subdued light at a temperature of 35 to 45 degrees Fahrenheit.
- ☑ REFRIGERATE biologics during field use.
- ☑ READ State regulations and consult your State Veterinarian in case of doubt about legality of vaccination – especially with live virus and modified live virus vaccines.

When Administering

- ☑ STERILIZE all instruments and vaccinating equipment that contact biologics; avoid chemical sterilization when using living vaccines.
- ☑ READ directions and precautions on labels and in package literature.
- ☑ ADMINISTER individual finished products separately. Mix only as directed.
- ☑ RESTORE only enough desiccated biologics for immediate needs. Destroy unused portions.
- ☑ SHAKE bacterial suspensions vigorously to assure an even mixture.
- ☑ DISINFECT the site of inoculation carefully.
- ☑ USE only the recommended route of administration and administer the recommended full dose.

After Administering

- ☑ RECORD the true name, serial number, expiration date, and manufacturer's name and license number of each product used. Identify animals treated.
- ☑ DESTROY empty biologics containers by burning or burying at least 18 inches deep in level ground.
- ☑ DISCARD unused portions of biologics; these easily become contaminated.
- ☑ INFORM clients about Federal regulations for withholding animals from slaughter following vaccination.
- ☑ REPORT immediately any adverse reactions to the Veterinary Biologics Division.
- ☑ PROVIDE for drugs to counteract anaphylactoid shock and be alert for such trouble.

labels and literature are GUIDELINES

Guidelines for use of U.S. licensed biologics are carefully spelled out on container labels and in accompanying literature. Manufacturers submit all biologic labels and literature for review and approval by USDA's Veterinary Biologics Division. Labels must show the true name of the product, serial number, name and address of manufacturer, a dosage table, quantity, storage instructions, precautions, and expiration date.

By following the basic guidelines provided for handling, care, and use of biologics, veterinarians can keep the products they use at maximum potency and maintain their safety and effectiveness. The very nature of biologics . . . the fact they are made from living disease organisms or their products . . . signals the need for care. Although striking advances have been made with biologics, proven procedures need to be followed for shipping, storage, and administration.

immediately report bad SIDE EFFECTS

Report abnormal and adverse side effects to vaccination as soon as possible to the veterinarian in charge of USDA's Animal Health Division in your State (probably located in the State capital). You also may write directly to USDA's Veterinary Biologics Division (see address on page 7), which will investigate all complaints involving a vaccine.

Describe the reaction precisely, and provide complete details on the case. Spell out the basis of all diagnoses and, along with reports on post-mortem examinations, blood samples, biopsies, etc., give the address of the laboratory where these analyses were made.

Keep especially close track of every dose of experimental drug furnished. State the type, manufacturer, serial number, and dosage of biologics and other drugs administered, along with dates of administration, kind, number and condition of animals vaccinated, diagnosis, and observation. Be sure to include the owner's name and address.

Practitioners aid biologics EVALUATION

Informal, but quite valuable studies can be done by practitioners to evaluate licensed biologics, particularly those marketed under "special" license. A special license certifies the safety, purity, and effectiveness of a biologic, just like a regular license, except that tighter control or further evaluation of a new product is needed. Here help from practitioners is obviously needed; but regularly licensed products also need field re-evaluation in light of new developments.

Evaluations are best made in herds divided into experimental groups managed separately. If that isn't possible, data should cover several years, not merely a brief "before" and "after" period. If two separate herds are used, management in both herds should be as similar as possible.

All participating animals should be clearly identified, and a complete history should be on record. Provide details on all disease problems, both in the herd under study and other herds in the area. Have fences and partitions secure enough to keep experimental groups carefully separated from other stock and from each other if the circumstances call for such separation.

Record all aspects of the trial carefully and promptly. Include details on medication used and results obtained, much as suggested above for reports on adverse side effects. Do not hesitate to submit favorable results as well as problem cases.

Address reports on veterinary biologics to:

Office of the Director
Veterinary Biologics Division
USDA Agricultural Research Service
215 Federal Center Building
Hyattsville, Md. 20782

assuring pure, safe, and effective BIOLOGICS

Veterinary biologics marketed across State lines must carry a U.S. Veterinary License Number on the label. The label is evidence that the product passed the requirements for purity, safety, and effectiveness stated in the Virus-Serum-Toxin Act of 1913.

The Act provides the Secretary of Agriculture with authority to regulate production and marketing of veterinary biologics in interstate and international commerce. Today, this regulatory work is carried out by the Veterinary Biologics Division, part of the Agricultural Research Service in the U.S. Department of Agriculture.

Requirements for biologics are precise. First a firm must acquire an establishment license, which certifies that plant, equipment, and qualification of personnel are adequate. The manufacturer must submit plans for production, testing procedures, and blueprints of equipment and production outlines. Second, the manufacturer must get a product license for each biologic he intends to market. He must submit test procedures, research data, cultures of organisms to be used, samples of the finished product, and proposed product labels.

After biologics are licensed, strict USDA surveillance continues. Inspectors make unannounced visits at manufacturing plants, check production and testing techniques, and collect samples for testing. Samples of each production lot are checked before the lot is marketed. Further check tests are done on products collected off the shelf in drug stores. Thus, the U.S. Veterinary License number is assurance to the practitioner that the biologics he buys have been carefully prepared.

All this information is carefully examined and correlated with check tests in the Division's own laboratories. Extensive field tests must be conducted to assure that a new product is pure, safe, and effective in practical use; such tests are conducted under the supervision of veterinarians with guidance from the Division.

LOOK FOR THE U.S. VETERINARY LICENSE NUMBER ON THE LABEL

- Purchase wisely
- Handle carefully
- Store properly
- Administer skillfully

Veterinary Biologics Division
Agricultural Research Service
U.S. Department of Agriculture

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